



DISTRIBUTING COMPANY, INC.  
P.O. Box 1596 TEL 520-281-1456  
TUBAC, AZ. 85646 FAX 520-281-1473

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Dockets and Management Branch [HFA-305]  
Food and Drug Administration  
5630 Fisher Lane, rm 1061  
Rockville, MD 20852

Office of Information and Regulatory Affairs  
Office of Management and Budget  
New Executive Office Building  
725 17<sup>th</sup> St. NW, rm 10235  
Washington, DC 20503

Docket Number: [02N-0278]

**Amex Distributing Co., Inc.** strongly believes that enhanced security of the U.S. food supply is crucial for the continued safety of U.S. consumers and their confidence in the fresh fruit and vegetables necessary for good health. My company imports fresh produce from Mexico through the port of entry in Nogales, Arizona. I am proud of our proven commitment to providing safe, high quality produce to American consumers, and I believe the provisions in the Bioterrorism Act of 2002 should ensure that we can continue this tradition.

However, the prior notice requirement for noon the day before product physically enters the United States will divert important government resources that already work to ensure food safety. Additionally, creating a duplicate data submission system that is not linked to the U.S. Customs database will hinder the communication efforts of government agencies regulating the border. Most disturbing, the proposed prior notice rules and separate database will increase the risk of intentional contamination to the U.S. food supply and will significantly limit my ability to deliver safe, quality produce to U.S. consumers.

The impact on my business will prove to be devastating if the prior notice rule is implemented in its current form. The growers I work with typically harvest produce in the morning and pack and cool the product in the afternoon. By late afternoon or evening, the shipments leave for the border to arrive the following morning. Almost everything the grower ships would not meet the 12:00 prior day requirement, and my company would be forced to wait up to an additional 32 hours to fill customers' orders. Given the highly perishable nature of produce, those customers would not want to wait for produce that has declined in appearance and quality and increased in ripeness to a point that some of it may become overripe before they have been able to sell it.

Therefore, they will look for other supply sources or pay significantly less for produce that would still cost the same amount to grow and ship.

An important inaccuracy to clarify is the FDA's assumption that my company controls the amounts of specified product that will be sent to the border before it is even harvested. On the contrary, we act as a sales agent for the grower who decides the quantities of product they have to sell. Additionally, the same amount of harvestable produce is not available everyday due to

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weather and plant conditions. Some days there may be more produce to pick than others, and neither my company nor the grower can predict the exact amount that may be ready for harvest on a given day.

The proposed rule will create foreseeable problems for other government agencies on the border that already have implemented antiterrorism systems. The FDA is proposing that all prior notice submissions include the Customs entry identification number. However, the entry number is assigned when information regarding a shipment is sent to Customs. Due to the fact that the exact weight of the truck is not usually known until a truck reaches the border, the FDA would require growers to file inaccurate, incomplete and false information to Customs. This is especially problematic as Customs does not permit electronic amendments on its system, unlike the FDA prior notice proposal that would allow for limited amendments. This proposal would require manual corrections and reentry by Customs when the specific entry is ultimately made, it would also increase wait times at the border, and it would increase the number of trucks inside the Customs compound waiting for secondary inspections. Important Customs and FDA resources that would be better devoted to antiterrorism efforts would be diverted to reconciling paperwork and incompatible databases.

One extremely dangerous result of the proposed prior notice rule will be the number of trucks idling on the side of unsecured highways waiting for their window of time to cross the border. My company would much rather receive the product as soon as possible in our secure warehouses than have trucks on the side of a highway vulnerable to intentional contamination by someone who wishes harm to the U.S. Given the lack of infrastructure and resources at the border to handle the flow of trucks during the produce season, wait times to cross can take anywhere from several minutes to 12 hours. If a shipment were to miss the original arrival time required by the prior notice rule, they would be forced to file an amendment and wait two hours to rejoin the line or would be forced to start the prior notice process over again.

**Amex Distributing Co., Inc.** wishes to reiterate that we fully support measures to ensure that we can deliver safe, secure produce to American consumers. However, we do not feel that the current prior notice proposal is an effective use of government and industry resources. More importantly, we feel that the prior notice proposal actually increases the chance that the food supply could be intentionally contaminated. Our company stands ready to work with the FDA in implementing a system that would fully leverage existing resources and in sharing our firsthand knowledge of current importing procedures to help the FDA develop a system that works. Please do not hesitate to contact us if we can be of any assistance.

Sincerely,

  
Charles Ciruli, President  
Amex Distributing Co., Inc.

Pres,